UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In Re: Bard IVC Filters Products Liability Litigation	) MD-15-02641-PHX-DGC))) Phoenix, Arizona) January 19, 2018)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

MOTION HEARING and STATUS CONFERENCE

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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P R O C E E D I N G S

THE COURTROOM DEPUTY: In the matter of MDL 2015-2641, Bard IVC Filters Product Liability Litigation, on for motion hearing.

Will the parties please announce.

MR. O'CONNOR: Good afternoon, Your Honor. Mark O'Connor, co-lead for plaintiffs.

MR. LOPEZ: Good afternoon, Your Honor. Ramon Lopez, also co-lead for plaintiffs.

MS. REED ZAIC: Julia Reed Zaic on behalf of plaintiffs' steering committee.

MR. LOPEZ: Do you just want the ones who are going to speak, Your Honor?

THE COURT: Sure.

MR. MANKOFF: Josh Mankoff on behalf of plaintiff.

MS. MATARRAZO: Hadley Matarrazo on behalf of plaintiff.

MR. ROTMAN: Steve Rotman on behalf of plaintiffs.

MR. NORTH: Good afternoon, Your Honor. Richard North on behalf of the defendants, and I'm joined by Mr. James Condo, and also from my office Mr. Philip Busman and Mr. Matthew Brown.

THE COURT: All right. Good afternoon, everybody.

MR. LOPEZ: Afternoon.

THE COURT: We're here to hold oral argument on four of the expert motions. Those are the motions directed at Hurst, Muehrcke, Betensky and Eisenberg. I don't have a preference in the order we follow them. I don't know if you do. If not, we can just go in that order.

I think we ought to argue them individually; do all the argument on Hurst and then all of the argument on Muehrcke, et cetera.

After we've done that, there are some matters I want to talk to you about in terms of case management, including some of the things that were raised in your joint report.

I've read the briefs on the motions. In fact, we have draft orders on all four, so I've spent time drafting orders as well, so I'm pretty familiar with the issues. You don't need to sort of start at ground one on acquainting me with what the issues are. Instead, I'd appreciate you focusing on the issues you think are most relevant now that it's briefed.

Why don't we start with Hurst. This is a defense motion.

MR. NORTH: Your Honor, Matthew Brown will be arguing that motion.

THE COURT: Okay.

MR. BROWN: Thank you, Judge Campbell. May it please the Court. In light of what Your Honor just mentioned with

your familiarity with the issues, I'd like to limit our argument to two principle issues we think may be helpful to the Court in considering the motion, the first being Dr. Hurst's opinions that Bard's filters, quote, have much higher complication rates in comparison to both permanent and retrievable filters, and, secondly, Dr. Hurst's opinions about minor caudal migration.

Taking the first opinion about the higher complication rates in comparison to both permanent and retrievable filters, we believe that Dr. Hurst is not qualified to offer that opinion. This opinion is crucially different from the other experts' opinions about the medical literature in this litigation. For example, the opinions that are offered by Drs. Kinney, Roberts, and Kalva where they focus on critiquing individual medical articles.

What Dr. Hurst is doing here is purporting to conduct what we like to call a meta-analysis in saying that he has -- conveying that he has conducted a systematic review and analysis of the literature concerning IVC filters. And, as Your Honor knows from science day, there are roughly two dozen IVC filters that have been available for use and several thousand articles in the medical literature concerning those IVC filters.

This type of meta-analysis is something that's typically done by somebody who is an epidemiologist or

somebody who has a very high level understanding of statistics. There's been nothing proffered by the plaintiffs to suggest that Dr. Hurst has anything in his background, training, or experience that would allow him to make these sorts of opinions. He's not an epidemiologist. He does not have a high level understanding of statistics. Rather, he's a practicing interventional radiologist in a community-based practice in Kentucky. And so therefore we feel that doctors -- Dr. Hurst's opinions about Bard's IVC filters have a higher rate of complications in comparison to all other permanent and retrievable filters should be excluded because he's not qualified to offer them.

We also think that opinion should be disqualified because it's unreliable. Dr. Hurst, in fact, has not conducted any kind of systematic review or analysis of the medical literature for IVC filters.

The articles that he cites in his Rule 26 report are limited in number, firstly, and, secondly, are almost all concerning Bard's filters rather than the other 20 or so IVC filters have that have been available for use.

Additionally, he focuses almost exclusively on an article by a Dr. Deso, which we attached as Exhibit B to the reply briefing. And Dr. Deso's article doesn't purport to identify which filters have higher complication rates than other filters, and it wasn't designed to do that.

What Dr. Deso's article was, was a review of the available medical literature, and he plucked out the articles that had the highest complication rates and put them into a table entitled Articles that Have the Highest Complication Rates. But he omitted all of the articles that have low complication rates. This is very different from a meta-analysis.

Bard is not aware of any article in the medical literature, the plaintiffs haven't identified any article in the medical literature, that purports to have conducted this meta-analysis of the available literature for IVC filters. And so for that reason we think his opinion should be inadmissible because it's not reliable.

Turning to the second issue, which is Dr. Hurst's opinion about unacceptable risk of caudal migration. We think that should be inadmissible because it's unreliable. Dr. Hurst is using a personal definition of caudal migration. He defines it as, quote, I mean basically a settling occurs with the filters, a splaying out of the legs, close quote, which he discusses in page 231 of his deposition, which we attached as Exhibit C to the reply brief.

Now, that definition is not found anywhere in the medical literature. The medical literature defines migration as movement of an IVC filter by more than 2 centimeters. And there's good reason for that. There are external factors

related to how the imaging is actually taken that could make a filter look like it's migrating when in fact it hasn't.

So, for example, a patient's body positioning will be different from one image to another image. A patient may be breathing in when one image is taken and breathing out when another image is taken. There may be minor differences in the angle of the camera that's taking the various images. Any and all of these issues can impact the way an IVC filter looks on the imaging and make it appear it migrated when it hasn't, which is why the medical community has settled upon this 2 centimeter definition for migration.

Bard has not found any literature, the plaintiffs haven't identified any literature that supports Dr. Hurst's definition of caudal migration.

And because Dr. Hurst is offering a personal definition of what caudal migration is, we think that that opinion should be inadmissible as unreliable.

We are not saying in cases where there's been a migration of more than 2 centimeters that his opinion should be inadmissible, because that is what is consistent with the available medical literature. Rather, it is his opinions in cases where the filter has moved less than 2 centimeters that we think should be inadmissible as unreliable.

Thank you, Your Honor.

THE COURT: All right. Thank you.

MS. MATARRAZO: Good afternoon, Your Honor. Hadley Matarrazo for the plaintiffs.

Dr. Hurst isn't doing a meta-analysis here. He didn't claim to do a meta-analysis, and one is not required for him to arrive at his opinion that Bard filters have a higher complication rate than other IVC filters. This argument is a red herring.

Dr. Hurst testified that what he did in arriving at this opinion is look at the medical literature. He relied on the Deso study that was discussed. He reviewed the 88 articles that underlie the Deso study, and he also conducted his own literature search and looked at the 70 to 80 articles that he pulled up in that search and reviewed them. And it is that that he relied on to arrive at his conclusion that Bard filters have higher complication rates.

The Deso study is an interesting study. It was conducted by three physicians, interventional radiologists, at the Stanford University Medical Center. The goal of that study, according to what the authors set out to do, was to evaluate the various FDA-approved IVC filter designs to determine which device specific risk -- excuse me, determine device-specific risks and help identify patients who may benefit from the ongoing followup versus prompt retrieval. In other words, which of these filters have higher complication rates and should be followed up and removed.

In doing this, what the authors did is they did a literature review. They identified 24 filters they wanted to look at. They then pulled what they thought were potentially relevant articles, which were nearly 1500 articles. From those articles they identified 88 articles and they reviewed all of those, and they compiled in a chart in that article the filters that had the highest complication rates based on the studies they looked at.

They also included a range of the complication rates in that chart, from the lowest complication rate they saw in a given study to the highest complication rate they saw in a given study.

And in doing so, they determined that across the board, particularly with regard to fracture but also with regard to tilt and perforation, that Bard filters had the highest complication rates.

And, Your Honor, under the *Daubert* 2 case, which we cite in our brief, this is sufficient to show -- the fact that this article was published in the peer reviewed literature is sufficient to show that it meets at least the minimal criteria of good science. This alone is sufficient for Dr. Hurst to rely on for the admissibility of his opinion.

THE COURT: Well, let me ask you a question about that last sentence.

It seems to me the fact that it's peer reviewed and

published would be a sound basis for Dr. Deso to give this opinion. But are you suggesting that any interventional radiologist can read this article and then give an expert opinion that is --

MS. MATARRAZO: I think --

THE COURT: -- just repeating what was the conclusion in the article?

MS. MATARRAZO: Well, yes, Your Honor. I think that, coupled with the other literature he's reviewed that has information about Bard's complication rates, as well as his own experience. And in addition to that, Your Honor, he also looked at Bard's own internal documents.

Bard's own internal documents, which are on his reliance list, things like G2 fracture analyses they conducted, caudal migration analyses, those also show their own filters have higher complication rates.

THE COURT: What did he do to verify the results in any of these articles or in any of the Bard documents?

MS. MATARRAZO: With regard to Deso, he looked at the 88 studies that underlied -- underlied that Deso article. So verified that that information was accurate based on the 88 studies that were in there, Your Honor.

THE COURT: Did he do anything to verify any of the information in any of those studies himself?

MS. MATARRAZO: Your Honor, all I'm aware of is he

reviewed the 88 articles that were underlying the Deso study.

THE COURT: Okay.

MS. MATARRAZO: With regard to the rate of G2 caudal migration, I won't go through all of the documents on his reliance list, but I want to point out one of them that I think is particularly important. There's a March 2nd, 2006, e-mail that attaches design failure mode effects analysis. This is a document -- or an analysis that Bard does where it predicts its own expected failure rates for all complications with regard to their filters, and this e-mail attaches one of those DFMEAs in which the employee, Bard employee, Natalie Wong, actually concludes that with regard to the G2 caudal migration that the rate that they're seeing with the G2 caudal migration exceeds their own anticipated rate in their DFMEA and actually says this is, quote, unacceptable, unquote. So it's not just Dr. Hurst that has this opinion, Your Honor.

THE COURT: Well, let me ask you a question on that as well.

It sounds as though you're suggesting that Dr. Hurst, as a doctor, can read an internal document at Bard that makes a factual assertion and then give an expert opinion the factual assertion is correct, without doing any study of it himself.

MS. MATARRAZO: Well, Your Honor, I think if you look at that in conjunction -- it is not just that one statement.

If you look at that in conjunction with the literature he reviewed, I think he's found support in both places for his opinion.

THE COURT: Well, the way that the defendants just argued it, and I didn't -- I read his report more than a week ago so I can't remember the answer to this question, but he seems to opine generally that there are higher complication rates based on Deso and the other articles, but he also says there's an unacceptable risk of caudal migration and he gets the words "unacceptable risk" right out of the Wong e-mail.

Besides the Wong e-mail, what specific information did he rely upon to reach a professional opinion that there was an unacceptable risk of caudal migration?

MS. MATARRAZO: Your Honor, he relied primarily on Bard's documents for that because the study didn't separate out caudal and cephalad migration.

THE COURT: I guess that gets back to my same question. You're saying a doctor can read an internal Bard document that makes a factual assertion and then come into a court and give that factual assertion as his professional opinion, without having done anything more. Is that what you're suggesting?

MS. MATARRAZO: Yes, to some extent, Your Honor, except it's also supported by the medical literature. So it's not the Bard document alone; it doesn't separate caudal and

cephalad migration. However, the literature -- there's evidence in the literature that Bard also has higher migration rates.

THE COURT: Does he identify specific articles he relied upon for that, in addition to the Wong document? I just can't remember.

MS. MATARRAZO: Yes, Your Honor. His reliance list has that and he testified about the Deso study as well as the 88 articles underlying them. Underlying the Deso study.

THE COURT: The Deso study, which I have in front of me, the table in it has just a general category for migration.

MS. MATARRAZO: That's correct, Your Honor.

THE COURT: That's all kinds, correct --

MS. MATARRAZO: Correct.

THE COURT: -- not just caudal?

MS. MATARRAZO: Correct.

THE COURT: Okay.

MS. MATARRAZO: Okay.

So, Your Honor, to the extent that you have any concerns about the testimony, the plaintiffs would just respectfully request that essentially, if it's a close question, that it be resolved at trial so that the evidence can be evaluated in the proper context in which it's, offered.

Thank you, Your Honor.

THE COURT: Let me ask you a question before you sit

down.

I'm looking at page 9 of Dr. Hurst's report in the Mulkey case.

MS. MATARRAZO: Yes, Your Honor.

THE COURT: I don't know if you have that --

MS. MATARRAZO: I do.

THE COURT: Okay. The way he states this higher complication rate opinion on that page in paragraph D1 is he says, "It is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with these filters."

That seems to be an opinion not about higher complication rates but about a failure to notify. And although I read your brief on this more than a week ago so I may be incorrectly remembering it, it seems to me you emphasized that, that what he's testifying about is what reasonable physicians would expect to receive, not about actual complication rates.

MS. MATARRAZO: Yes, Your Honor. To the extent that the complication rates are higher, Your Honor, that is certainly something that I think Dr. Hurst is qualified to opine that a reasonable physician would want to know. And I think that's something Your Honor actually resolved in the prior order with Kinney, Kalva, and Roberts, that physicians such as these interventional radiologists are qualified to say

what they -- what they would expect -- the information they would want to have or expect to have from Bard related to the risk of their IVC filters.

THE COURT: It seems to me that there's a difference between those opinions. On one hand, a doctor could come in and say something like if there is a higher complication rate, I would want to know it as an interventional radiologist and I think my patient would want to know it; it should be disclosed. Which may go to the failure-to-warn issue.

It's a different thing to come in and say it's my opinion that there is a higher complication rate for these filters.

Are you proposing that he do both of those things?

MS. MATARRAZO: We are proposing that he do both. But we understand if Your Honor's going to limit that testimony to what a reasonable physician would expect to be notified about.

THE COURT: Okay. All right. Thank you.

MS. MATARRAZO: Thank you, Your Honor.

MR. BROWN: Nothing further, Your Honor.

THE COURT: Let me ask you a follow-up question on what was just asked.

Do the defendants object to Dr. Hurst coming in and saying, in effect, if there are higher complication rates, interventional radiologists and their patients would want to

be told that information?

We need you at a mic, if you would, please.

MR. BROWN: I think leaving aside the foundational issue of whether there are, in fact, higher complication rates, which would take away what we've argued previously about him not being qualified and that opinion not being unreliable, but in that hypothetical situation, if we are to assume Bard's filters have higher complication rates, then we think that that would fall under Your Honor's previous ruling for Drs. Kinney, Roberts, and Kalva that that would be something that Dr. Hurst would be able to speak to the jury about what a reasonable physician would want to be informed about from a medical device manufacturer.

THE COURT: Okay. All right. Thank you.

Let me make a note here before we talk about the next one.

Okay. Let's take up Muehrcke next. Am I pronouncing that correctly?

MR. NORTH: I think so, Your Honor. Dr. Muehrcke.

THE COURT: Okay.

MR. NORTH: Your Honor, the motion to exclude certain opinions of Dr. Muehrcke has six separate points. Four of those points, however, I believe have been addressed by this Court already in previous *Daubert* rulings, and those would be our contention, number one, that Dr. Muehrcke is not qualified

to offer design opinions. I believe the Court has already ruled upon very similar factual circumstances and assertions in the context of the order regarding Drs. Kinney, Roberts, and Kalva.

The second point is our argument that Dr. Muehrcke improperly adopts opinions of other experts. The Court addressed a very similar argument in the opinion regarding Dr. Kinney.

The third has to do with the subject the Court just raised in the last motion discussion which is the testimony regarding physician expectations, and this Court has already addressed that in the orders of Dr. Kinney and Dr. Kessler and Dr. Parisian.

And the fourth point I believe the Court has covered already is our contention that Dr. Muehrcke should not be allowed to opine regarding corporate motive, intent, and state of mind, and this Court has already indicated in the order regarding Drs. Kessler and Parisian the limitations that will be put on testimony to that effect.

On those points that have been covered, though, I would like to adjust just a couple of additional points unique to Dr. Muehrcke, and that's the fact that as far as his design opinions, which talk about everything regarding from migration resistance to weak anchoring hooks to lack of radial force, the plaintiffs attempt to justify those opinions by saying

that he is testifying based on his clinical experience. However, I wanted to point out his opinions go far beyond his clinical experience, quote, unquote, and deal with engineering and design issues that somebody who's a cardiothoracic surgeon like Dr. Muehrcke is not simply qualified to give.

The other point I would raise regarding issues that have already been covered by the Court --

THE COURT: Before you leave design, since you just mentioned it, let me ask you a question on what you just said.

Dr. Muehrcke clearly does state the opinion that the filters had inadequate migration resistance and lack of strength and stability caused by weak anchoring hooks and lack of radial force and inadequate leg span. But he then says in the next sentence, "In reaching this opinion, I reviewed Ms. Booker's medical records and radiology and performed a differential diagnosis, and there is no other reasonable cause for the failures of the filter."

I agree with you that he's not a metallurgist, he's not an engineer, he's not a product designer, and he can't give opinions from that standpoint. But as a doctor who has dealt with many cases of implanted filters and removing filters and problems with filters, does that qualify him to say, look, I've done this a lot, I've looked at her medical history, I know what causes filter problems in human bodies, and looking at her medical history I can't identify any other

potential cause of this problem than a defect in the design of the filter?

MR. NORTH: Well, Your Honor, I would submit that that -- his practical experience as a physician qualifies him to give an opinion that the filter failed and how it failed as far as did it fracture or did it migrate. But then to take that further leap and to say it migrated or it fractured because of a lack of radial strength, because of weak anchoring hooks, things that he has never assessed and does not have the competence or experience in the engineering fields to assess, that's the leap where he goes too far.

If he wants to give an opinion her medical condition was caused because this fractured and this migrated and I see that, that's certainly within his experience. But to say what engineering attributes of that filter led to that complication, he's simply not qualified, we would submit.

THE COURT: Okay. Thanks.

MR. NORTH: Turning to another opinion that this Court has already addressed but I just wanted to point out one thing different with Dr. Muehrcke, and that has to do with the adoption of opinions of other experts.

This Court ruled in the order regarding Drs. Kinney, Kalva, and Roberts that it was appropriate there, although I believe the Court said something to the effect that they couldn't simply narrate or parrot those opinions, it was

proper for them to rely upon those opinions. But here we have Dr. Muehrcke going one step further. He adopts and professes as his own Dr. Kinney's opinions, and -- from that report, and he basically tries to embrace those and endorse those.

Now, as we know, Dr. Kinney's report is based in large part on Dr. Kessler's report. But Dr. Muehrcke admits he never read Dr. Kessler's report.

So he's adopting the opinions of one expert -- or one group of three experts, Drs. Kinney, Roberts, and Kalva -- and their endorsement of another expert's report who he has not read. And we believe that that is an improper attempt to sort of adopt the expert opinions of someone else, particularly when, like Dr. Muehrcke here, he's made no effort not only to corroborate but even to read the central focus of Dr. Kinney's report.

Turning to the two newer issues raised by Dr. Muehrcke's -- motion regarding Dr. Muehrcke, the first one is very similar to what the Court just discussed regarding Dr. Hurst, and that has to do with Dr. Muehrcke's opinion that the G2 and the Eclipse had, quote, acceptable, unquote, rates of caudal migration.

It's very clear that Dr. Muehrcke has made no independent analysis of the rate of caudal migration. He can't cite to medical literature dealing specifically with caudal migration.

He claims to rely on the analysis and conclusions of Dr. Betensky, the statistician, but he admits he's never read Dr. Betensky's report. He simply -- and then he goes further and says, well, the Bard rate is unacceptable but I don't know or I refuse to say what would be an acceptable rate, other than as close to zero as possible.

He has simply made no analysis, no effort, to determine the rate of caudal migration with regard to Bard's G2 filter. He's simply taken that statement out of the Wong e-mail without an understanding of the context, the nature of that particular analysis that was being done, what "unacceptable" meant in that particular engineering context. He doesn't know. He hasn't studied it. He simply has endorsed it and tries to float this large opinion that there's an unacceptable rate of caudal migration when he's done absolutely no background work to make that determination.

The one other unusual or unique issue -- not usual but unique to Dr. Muehrcke, is really specific to only one of the bellwether cases. Although possibly to the Booker case because some of his opinions bled over to Booker, and that has to do with Ms. Hyde and his opinions regarding her future risk of arrhythmia. And he also makes some statements about Dr -- I mean Ms. Booker in that regard, but they're focused mostly on Ms. Hyde.

The plaintiffs keep saying in their brief that it's

okay for him to give these opinions because he's a cardiothoracic surgeon and you don't have to be a very specific -- in a very specific medical field to necessarily give opinions in this area. But that is not the basis of our argument, Your Honor.

The basis of our argument is his own admission in his deposition that he would have to defer to an electrophysiologist to quantify the future risk, he would have to defer to an electrophysiologist to determine whether automatic implantable defibrillator was even necessary with Ms. Hyde. He stated these opinions in his report, but when being deposed admitted that he would have to defer to the true expert in that field on those areas. So by his own admission, Your Honor, he's not qualified to give those opinions.

If the Court has no further questions, that concludes what I wanted to point out.

THE COURT: Thank you.

MS. MATARRAZO: Your Honor, I'm going to start with the design argument. I think this Court has already decided that and I just wanted to touch on that briefly, that Dr. Muehrcke isn't going to be offering any opinions such as the one that this Court -- the ones that this Court describes on page 10 of the prior order.

What Dr.--

THE COURT: Which order -- which order are you

referring to?

MS. MATARRAZO: I'm sorry. The Kinney, Kalva, and Roberts order. If it's okay with the Court, I'll just refer to it as the prior order rather than trip over the names every time I have to say it.

What Dr. Muehrcke does, and it was just discussed so I won't go over in detail, but it gives opinions about performance flaws from a clinical perspective and and how -- what the clinical effect of those particular issues are with the filter and how that manifests in the plaintiff.

And so I understand the Court on page 11 of that prior order didn't say this testimony was something the Court was necessarily going to allow in, but I believe what the Court wanted to do is hear that testimony in the context it was going to be offered at trial and make that decision, and plaintiffs would respectfully request, to the extent Dr. Muehrcke is going to offer any of that testimony at trial, that it be handled at that time. And certainly there are ways to question that witness outside of the presence of the jury to establish that there is -- that that -- that the opinion being offered and is reliable and that the witness has -- is qualified to give that opinion.

With regard to the reliance on other experts, Dr. Muehrcke -- what Dr. Muehrcke said is he reviewed, agrees with, and adopts the opinions of Kinney, Roberts, Kalva, and

Eisenberg. None of Dr. Muehrcke's opinions rely solely or even primarily on the reports of other experts. Nor does he intend to parrot those experts' opinions. So we believe that the prior order governs in that situation.

With regard to the argument on the caudal migration rate, it's pretty much the exact same argument I just made with regard to Dr. Hurst, so I won't reiterate that with the Court. The only thing I want to point out is -- well, two things: The Wong document really speaks for itself. And with regard to Dr. Betensky, he had not read her report at the time that he signed his report. My understanding is that he had read her report prior to his deposition and that what Dr. Muehrcke essentially said is that his opinion is supported by Dr. Betensky's report, that she found the same thing.

Okay. So with regard -- I think that leaves us, really, just with Plaintiff Hyde. And in this situation what Dr. Muehrcke did is he offered the opinion that as a result of the failure of her G2 filter and resulting heart surgery, she's at risk for future arrhythmias and automatic implantable cardiac defibrillator and sudden death. He's a cardiothoracic surgeon. I think he's certainly qualified to opine about future risks that a patient who has heart surgery would face.

The defendants' real issue here is that they didn't quant- -- he didn't quantify the risk. When he was asked to quantify the risk, he said an electrophysiologist would be

better suited to quantify that risk.

Physicians make risk assessments like that all the time without quantifying the risk in their daily practice; a patient's at an increased risk of a particular outcome and treat that patient accordingly.

The fact he didn't quantify the risk and said he's not the person that should quantify that risk doesn't disqualify him from giving his opinion. This is really an issue for cross-examination, Your Honor.

And unless Your Honor has any questions, that's all I have on Dr. Muehrcke.

THE COURT: Okay. Thank you.

MS. MATARRAZO: Thank you, Your Honor.

MR. NORTH: Nothing further, Your Honor.

THE COURT: Okay.

All right. Let's talk about Dr. Betensky.

MR. NORTH: Your Honor, Mr. Busman will argue this motion.

THE COURT: All right.

MR. BUSMAN: Good afternoon, Your Honor. May it please the Court. I understand the Court is quite familiar with the briefing and has largely made up its mind on how it's going to rule on this. I will, however, highlight a couple of issues I think are particularly important with respect to Dr. Betensky's opinion.

The first, of course, has to do with Dr. Betensky's failure to consider data for the Simon Nitinol filter for the ten-year period prior to 2000 when it was on the market. To review the bidding a bit, Dr. Betensky calculated what she styled a reporting risk ratio. She then inferred, based on that reporting risk ratio, something called a risk ratio.

Now, in order to do this, she took a look at adverse events reported for each of the retrievable filters starting at market introduction carried through all the way to the present or when they were removed from the market. For the Simon Nitinol filter, however, she omitted a decade's worth of adverse events.

When we confronted her at deposition with this omission, she clearly admitted that failure to consider these data could have invalidated her opinions entirely.

In fact, as we quote in our papers, she testified that the number she calculated could have gone up, could have gone down. She has no idea where those numbers would have gone.

The fact of the matter is, Your Honor, this is not an issue that can be remedied on cross-examination. Any opinion with respect to an RRR let alone an RR is now completely speculative. She simply doesn't know the answer. It runs afoul of Rule 702's prescription. You've got to have sufficient facts and data. She simply does not.

Another point that I would like to highlight is Dr. Betensky's failure to employ reliable assumptions.

THE COURT: Before you leave the Simon Nitinol filter --

MR. BUSMAN: Yes.

THE COURT: -- what you argue in your brief and in your reply is that it is, quote, entirely possible, close quote, that this decade of data would change the result of her analysis.

You've got the data. You've got a biostatistician expert. I don't see any suggestion that you had them look at the data to see if, in fact, it did change the result of her analysis.

MR. BUSMAN: Your Honor's correct. We didn't employ that analysis. But it's plaintiffs' burden. They're the ones who are moving to introduce this evidence. They're the ones who had to account for it. We don't have the burden of proof on that issue. If they want to present this evidence to the jury, it has to be both relevant and reliable. She simply didn't account for it.

THE COURT: Well, but if Dr. Betensky says, as I think she did, that her review of this data suggests that the Weber effect doesn't apply, this isn't an instance where there are more reports up front and fewer later, in fact she says the data tends to suggest it's the opposite, there are fewer

at the start and more later, and therefore she doesn't believe that the data from that ten-year period would show any different result because it would have been lower, not higher, for the Simon Nitinol.

If she states that opinion and as a biostatistician says "I'm comfortable with my opinion because of that fact," isn't that for the jury to evaluate whether that's a reasonable basis for her to stand on the Simon Nitinol data she's used?

MR. BUSMAN: No, Your Honor, I don't think so. With due respect, that is runs counter to her clean admission that she has no idea what her calculations would have shown. She simply doesn't know the answer. And she admitted cleanly that she would have employed these date had she had them. So, no, I do not think it is a question for the jury. It is entirely speculative at this point.

THE COURT: Okay.

MR. BUSMAN: Now, with respect to the second issue I'd like to highlight, having to do with the assumptions that she employed, as we set forth in our brief, Dr. Betensky explains that assumptions are necessary. They're necessary to go from the RRR she calculated to any inference with respect to an actual RR. And she further explained that the reporting risk ratio is not the quantity of interest in this case, it's not at all. It's a crude estimate. It's truly the risk ratio

that is informative.

Now, in order to extrapolate at all from a reporting risk ratio to a risk ratio she was required to employ certain assumptions. Now, plaintiffs have not contested the portion of our brief where we explain potential differences between detection of adverse events in the Simon Nitinol permanent filter and various retrievable filters.

In order to make those assumptions requires collaboration with the subject matter expert. This is something Dr. Betensky does routinely in her professional capacity outside of the courtroom. She collaborates with subject matter experts. They provide the assumptions, she runs the analysis. That did not happen in this case. She simply employed assumptions that made sense to her.

She's not a medical doctor. She's not an expert in these products. And because of that, any assumptions she employed are simply ipse dixit. They just seemed reasonable and she employed them. And, in fact, when we questioned her about this at deposition, she admitted she didn't control for any of those issues.

For example, she claims she did not have the data to render an opinion one way or another whether differences in detection would have impacted her opinions.

She also testified that she didn't have any information and therefore could not control for the

possibility that notoriety surrounding, for example, lawsuits related to these products may have impacted reporting.

I want to take a step back with respect to notoriety and increased reporting. Your Honor mentioned the Weber effect. I find plaintiffs' position on the Weber effect to be a little bit curious.

Dr. Betensky herself in her report described the Weber effect. She's the one in the limitations sections of her report who first put it out there. It was only when Bard posited that it was entirely possible there could have been increased reporting when the Simon Nitinol filter first hit the market that plaintiffs have countered it. But these assumptions are simply things she didn't account for and render her opinions speculative and unreliable.

The final point I'd like to make -- again, I'm limiting this to issues I think might assist Your Honor in completing the order -- to be clear, Bard is not attacking MAUDE data at large. That's not anything that we're intending to do here. What we are attacking is the manner and the way in which Dr. Betensky employed it.

The briefs are replete on both sides with admonitions on the MAUDE home page and/or from FDA guidance documents cautioning -- cautioning anyone from using MAUDE data in a way to compare rates.

For example, in a direct quote from Dr. Betensky's

rebuttal report in this case with respect to Dr. Thisted and I believe the same language also appears in her rebuttal to Dr. Feigal, FDA notes such comparisons are subject to substantial limitations and interpretation. As a result, FDA suggests a comparison of two or more reporting rates be viewed with, they use the words "extreme caution." They go on to say any such comparison of rates is generally considered exploratory and hypothesis generating.

In essence, MAUDE data enables the reviewer to come up with a question that then must be answered using additional or other data.

Dr. Betensky did it exactly the opposite way.

She had a pre-determined hypothesis that she attempted to confirm with these data. And that is specifically what FDA admonishes that a party should not do.

Unless the Court has any further questions, that concludes my presentation.

THE COURT: Okay. Thank you.

MR. MANKOFF: Good afternoon, Your Honor. Josh Mankoff for plaintiffs.

Before I dive in and respond specifically to the points just raised, I wanted to take one step back and frame the issues here.

Counsel just ended by talking about the MAUDE data. Dr. Betensky didn't look at the MAUDE data, which, by the way,

the FDA in its 2005 guidance specifically states they recommend that sponsors calculate adverse event reporting rates.

So despite some cautionary language, when you don't have access to the denominator to calculate a ratio, they do recommend that manufacturers do this analysis.

But in any event, she relies on Bard's own data and she models her analysis after the analysis that Bard did internally. So for them to get up and say this is so unreliable as to be not as admissible is to say their own analysis is not good. And they make marketing claims based on these analyses, and so perhaps plaintiffs could get directed verdict on some of those claims.

One other background point is that Dr. Betensky actually offers three opinions and Bard doesn't really offer any argument for the first two of her opinions that they should be excluded, but they do claim in their reply in footnote 8 that they are asking for exclusion of those opinions.

The Ninth Circuit has said that argument -- it's not even an argument, but a claim made for the first time in reply need not be considered. So I'll leave those aside. Those are her bench test analysis looking at the migration resistence bench testing and she also does an analysis of the design failure mode and effects analysis documents which are, as you

heard before, Bard's predictions about failures that are going to occur with their filters.

Dr. Betensky did, in fact, consider each of the limitations that she outlined in her report and she used statistical techniques to assess whether they're occurring or not.

So, for example, whether there's -- Bard speculates there's maybe detection bias or reporting bias and she looked at the variability across adverse events and strong evidence across time periods and across different adverse events and different severities to conclude that it's unlikely that this is happening. And the judicial reference manual on epidemiology counsels that this is appropriate science to use in litigation.

Similarly, she looked at some of the adverse events are unlikely to be found due to detection. For example, a filter death caused by a filter or filter embolization is detected because someone comes in with symptoms or has died. So it's not about any kind of surveillance that's detecting these differently in one filter or another.

With regard to the SNF data, as you noted, they're speculating this is in effect. If they have data to show it would influence their results, they ought to come forward at trial and cross-examine her on it.

This ties in with the speculation about the Weber

effect, which, again, she looked at and she considered. She conducted a sensitivity analysis to see if she varied various assumptions would that change her conclusions, and she found, no, they don't.

She -- after the issue of this SNF data before 2000 was raised at her deposition, she looked at it, and so did Dr. Eisenberg, and they both concluded there are very, very few -- that's a quote from Dr. Eisenberg's deposition, "very, very few" -- adverse events that occurred during that time period and they wouldn't change the conclusions.

So while it's not in Dr. Betensky's report, if she's asked at her dep- -- at trial about these events, she will be able to say that she looked at it, she saw, for example, five migrations occurred in that whole first decade and three perforations and I believe one fracture in that whole first decade. So even if you assume there were no sales during that decade, they would not influence her conclusions.

And one of her sensitivity analyses was to assume there were unreported events for SNF. She added five events to every SNF failure that she looked at. And she concluded that that did not change her conclusions either. So there really is nothing there.

Dr. Eisenberg was asked at his deposition whether he had any idea about the data before 2000. He testified, yes, he looked at it and they wouldn't change the conclusions based

on his expertise in epidemiology.

Counsel said that the reporting rate ratio, which is what Dr. Betensky calculated, is not of interest. It is of interest. It's relevant. It goes to notice, it goes to signal that there's a very great signal of a problem here and what Bard should have done based on that information, what actions they should have taken. So while she does then take a step and say, well, this is based on her statistical expertise, it says there's a problem with these filters, that there's higher failures with the Recovery and later filters, both opinions are certainly relevant and ought to be admissible.

I wanted to provide a little context on the speculation about the Weber effect because the idea of this effect stems from a 1987 paper that was done in the UK, and it was looking at drug adverse event reports not at medical devices, and there's a big difference there because with drugs there's almost always a question about whether the drug is causing the adverse event or whether it's a coincidence.

In 1987, in UK, the regulatory authority there encouraged physicians to report adverse events for the first two years that a drug was on the market. So it's not a big surprise that when Dr. Weber looked at this information he saw that there was an increase and then it tailed off after about two years. But what he found was this only occurred for

non-serious events. When he looked at serious adverse events he found it was consistent across time.

So you take the fact we're looking at drugs -- at devices here and serious adverse events, there's -- and there are no papers Bard has come forward with that this effect occurs with medical devices. When it's been looked at in the US recently, it doesn't occur as much for drugs either. So speculation that this is occurring and having an effect is really on Bard to come forward with some evidence that this is occurring. Again, that's an issue for cross-examination.

Finally, with respect to whether clinical review is necessary and the idea that statisticians usually collaborate with other experts in the field, that is occurring here but it has to be done a little differently in the context of litigation. So Dr. Betensky writes a report and, as you heard, others have reviewed it and relied on it, and in particular Dr. Eisenberg and Dr. Kessler have rendered their clinical -- have used their clinical experience to render opinions about whether any of these speculated biases would be occurring and they concluded it's unlikely any of those alone or in combination could explain the results that are being calculated here.

Finally, the case law and the peer review literature support use of adverse event analysis comparative rates using MAUDE data, and in particular I'll direct your attention to

Exhibits 32 through 36 where we cite papers that have done similar analyses, and that's support for the reliability and admissibility of this type of opinion.

If the Court has no further questions, I would rest.

THE COURT: Thank you.

MR. BUSMAN: May I approach?

THE COURT: Yes.

MR. BUSMAN: Your Honor, just a couple quick points as I wrap up.

Regarding Dr. Betensky's failure to collaborate with the subject matter expert to determine whether her assumptions were reliable or not, counsel mentioned that both doctors Eisenberg and Kessler took a look at her assumptions and validated them.

I don't recall anything in either of those reports discussing whether or not Dr. Betensky's assumption about detection of asymptomatic adverse events are valid. And, in fact, neither Drs. Eisenberg nor Kessler are even proffered as subject matter experts. So I'm not sure how they would even be qualified to vet the assumptions that she employed.

With respect to Dr. Eisenberg's review of the data prior to 2000, I think Your Honor would appreciate that it is not Dr. Eisenberg but rather Dr. Betensky who would have to review these data. Dr. Eisenberg never rendered an opinion in his expert report having anything whatsoever to do with

Dr. Betensky's actual analysis. All he ever did was quote it chapter and verse and say he agreed. We never had an opportunity to cross-examine Dr. Betensky because she never considered these data. And it's not possible to do that on the stand. She'd have to run her calculations, she'd have to come up with her numbers, and we'd then have to examine her. That's not something that can be practically accomplished during the trial, which is why it is not a cross-examination issue.

With respect to plaintiffs' distinction between Bard's data and the data coming from MAUDE, I suggest it's a distinction without a difference. Plaintiff -- excuse me. Dr. Betensky herself quotes liberally from the FDA guidance documents in support of her opinions and we're simply pointing out to the Court other aspects of the guidance that run counter to what it is she's attempting to accomplish.

And, finally, it was Dr. Betensky's own words that the reporting risk ratio is not the calculation of interest. That's not counsel's argument, that's her own testimony.

Unless the Court has any further questions, that will complete my presentation.

THE COURT: Okay. Thank you.

All right. Let's talk about Eisenberg.

MR. BUSMAN: I'll stay here.

MR. ROTMAN: I'll be arguing for the plaintiffs on

the Eisenberg motion, but would the Court allow a short break so I can be here? I need to use the men's room.

THE COURT: Sure. We'll come back in ten minutes.

(Recess taken from 2:00 to 2:12.)

THE COURT: All right, let's talk about Eisenberg.

MR. BUSMAN: Good afternoon again, Your Honor.

I'll limit my presentation to the issues I think might be of interest to the Court as it wraps up completing its order.

To review the bidding just a little bit, Dr. Eisenberg is by no stretch a subject matter expert in IVC filters. He admits it. He's never implanted a filter. He's never retrieved a filter. He's never prescribed a filter. He's got nothing whatsoever to do with filters.

The Court has already ruled on virtually everything that pertains to our argument for the exclusion of Dr. Eisenberg with respect to ethics, and the Court's order on Drs. Parisian and Kessler, in particular page 17 in the Kessler section, the Court held that neither side would be permitted to offer an expert witness to render opinions sounding in ethics. But that's exactly what Dr. Eisenberg is doing notwithstanding plaintiffs' claim to the contrary.

In the opening portion of Dr. Eisenberg's report he delineates the foundation for his opinion, the various documents that underlie his opinions and form the foundation

for them. They all sound in ethics. Most of them have the word "ethics" in the title. He admitted that the driving force for the majority of his opinions are that companies should be honest, companies should be responsible, companies should follow up the way a responsible and ethical manufacturer would do.

So, as I said, the Court's already ruled on this -- and the Trasylol court that excluded Dr. Eisenberg for virtually the same reasons contended with the same argument. Plaintiffs in that case also claimed that Dr. Eisenberg was not rendering ethical opinions. But the court looked beyond plaintiffs' claims to the substance of his actual opinions and determined they were ethical nonetheless.

With respect to Dr. Eisenberg's myriad opinions on physician and patient expectations, the Court again in the Parisian-Kessler order ruled that Dr. Parisian -- and this is on page 8, Dr. Parisian was not allowed to talk about physician expectations. And it's important to note Dr. Parisian is not a subject matter expert just like Dr. Eisenberg is not a subject matter expert, which distinguishes this, for example, from the Kinney, Roberts, and Kalva opinion.

Now, with respect to Dr. Eisenberg's review of corporate documents, he reviewed those documents to foster his ethical opinions. He's got no basis or foundation for

reviewing any of Bard's internal corporate documents. He's not a regulatory expert, not a subject matter expert. There's nothing that he can add to these documents that sound in any experience that he has that could inform the jury and help them decide any issue.

The only thing that would be left here are his epidemiologic opinions. Dr. Eisenberg is an epidemiologist. That is true. But he reviewed various articles in the literature, not to give some opinion on the safety of these devices at large but, as he describes in paragraph 172 which sums up his review of the literature, quote, this is the type of investigation and communications that physicians expect a responsible manufacturer to undertake. The Trasylol court excluded that opinion. And, again, this sounds in ethics and this Court has already ruled that ethical opinions are not going to be admissible in this case.

Unless the Court has any questions, that concludes my presentation.

THE COURT: Okay. Thank you.

MR. ROTMAN: Good afternoon, Your Honor. Steve Rotman. I'll be arguing for the plaintiffs on the Eisenberg motion. I'm going to start with the issue of ethics opinions.

Plaintiffs agree that Dr. Eisenberg is not permitted to give ethics opinions. We're not challenging the rule. What we're challenging is the characterization of his opinions

as ethics opinions.

The plaintiffs' claims that Dr.-- the plaintiffs claim and contend that Dr. Eisenberg's opinions are not ethics opinions and Bard is arguing that we are blatantly side-stepping this issue and attempting to recast what his opinions are to call them anything else.

The fact is that we're not doing that at all, that we're simply reporting and repeating what Dr. Eisenberg has stated in his report repeatedly. And that is what distinguishes this case from the Trasylol case.

So first, to place this issue in context, Dr. Eisenberg's opinion is 47 pages long, over 200 paragraphs, and covers a wide range of issues and offers many different opinions about Bard's filters, that are not even remotely ethics opinions. Essentially, it is the opinions that begin with the words "Bard should have" that are at issue.

And as to those "Bard should have" opinions, they almost entirely fall into two categories. Those categories are opinions about what Bard should have done to learn more after it learned about filter fractures and migrations, and what information about those problems Bard should have passed along and disclosed to doctors.

Bard claims that these opinions are actually based on Dr. Eisenberg's undisclosed views about ethical obligations because it's clear that in the report itself there -- the

basis for these opinions are not stated as ethical obligations.

Plaintiffs suggest that Dr. Eisenberg's report itself provides the best evidence to help the Court answer the question about what -- how to characterize these opinions. What we learned when we read that report is that throughout the report Dr. Eisenberg provides the basis for these "Bard should have" opinions.

And to simplify the task for the Court of sorting this out given the length and level of detail in Dr. Eisenberg's report, I have created a compendium of excerpts, which I'm prepared to give to the Court, and to counsel, which is just four pages long and provides excerpts and paragraph numbers, that makes it clear and will aid the Court in deciding how to in fact characterize these challenged opinions, and to determine whether they're in fact ethics opinions, which should be excluded, or whether they're based on other foundations which are permissible and entirely appropriate.

So I'm going to offer this compendium when I wrap up at the end of my presentation, and I suggest that a review of these excerpts will make it clear that the challenged opinions are based on four grounds, all of them appropriate:

One, what is required for patient safety.

Two, what is required for informed consent.

Three, what is required based on the principles of pharmacovigilance.

And, four, what is required based on Bard's own articulated internal standards.

None of these are ethics opinions grounds. All of them are within the expertise of Dr. Eisenberg. He is a clinical epidemiologist. And he explained at his deposition and in his report, and we think we covered in our brief, that the focus of clinical epidemiology is patient safety, and his focus in his work over decades has been medical device, patient safety, clinical epidemiology.

So it should be clear to the Court after reviewing these excerpts and any other part of Dr. Eisenberg's actual report that there is no basis to conclude that these "Bard should have" opinions are actually somehow masquerading as Dr. Eisenberg's views on Bard's ethical obligations.

For example, on paragraph 42 of his report he states that "The standards that underlie my opinions in this report for monitoring for safety signals, following up on those signals, and disclosing important safety concerns to doctors form the foundation of our medical system, are essential for informed consent and patient safety, and constitute generally accepted standards for pharmacovigilance."

And in paragraph 37 --

THE COURT: Well, let me interrupt you for a minute.

After that statement he cites an FDA guidance document.

MR. ROTMAN: On pharmacovigilance.

THE COURT: No. It's the World Health Organization he cites on pharmacovigilance. But he cites those too.

He's not an FDA expert and doesn't claim to be a pharmacovigilance expert. He's just citing other sources.

Are you suggesting that you should be able to argue to the jury that what the World Health Organization has said in a document establishes the legal standard that Bard must have complied with in this case?

MR. ROTMAN: No.

THE COURT: Isn't that what he's saying when he says they should have?

MR. ROTMAN: No. What he's saying is that based on his expertise in clinical epidemiology and expertise as a clinical physician in interventional cardiology and his knowledge of patients having the very problems that these filters are being used for and his treatment of these patients with alternative therapy, that is -- that is the anticoagulation, and his having patients in his practice that have these filters, that what is required for patient safety, what is required for informed consent, what other physicians need and expect for informed consent, and what is consistent with the internal standards articulated by Bard's own

president, former head of regulatory, former director of research and development, they -- they are mirroring what Dr. Eisenberg is saying. And what Dr.-- and with respect to pharmacovigilance, pharmacovigilance and clinical epidemiology go hand in hand. It is the foundation of what pharmaco-- of what clinical epidemiologists are concerned with. Pharmacovigilance is not his specific field of expertise, but he is quite familiar with it.

THE COURT: Well, let me -- let me ask you a question that is at the heart of my concern over his opinion. Let me make a note, first.

The way you characterize his opinions are "Bard should have." I agree he says that throughout his report.

"Bard should have" is a different way of saying "Bard had a duty to." Or "Bard had a responsibility to."

When I read his report -- I haven't read all of it. I read the first 50 paragraphs that are the summary of his opinions, and I've looked at other parts, but those are the ones I read line by line.

He repeatedly asserts Bard should have done this, Bard had a responsibility to do this.

MR. ROTMAN: Yes.

THE COURT: When I ask the question what is the source of the responsibility he is citing, the duty he is citing, the ones I can see are he cites American Medical

Association Code of Ethics for doctors and practice guidelines from the American College of Radiology.

Those are standards for doctors to adhere to, not medical device manufacturer.

MR. ROTMAN: Your Honor --

THE COURT: Let me finish my thought and have you comment on all of it.

MR. ROTMAN: I thought you were done.

THE COURT: He then cites that one FDA guidance document and the World Health Organization document. But he's not an expert in either of those areas.

It seems to me what it comes down to is his opinion is, as a doctor, Bard should have done these things. Why is that relevant in this case? The jury is not going to be instructed you are to hold Bard to the standard that a reasonable doctor would have applied. That's not going to be the standard in this case.

MR. ROTMAN: Your Honor, as it will perhaps become clearer to the Court when you review the four-page compendium, the phrasing of the opinions comes in various forms, but it's frequently "Bard should have." That's not the critical point. The critical point that Dr. Eisenberg is making is that what it is -- what is necessary for patient safety is followup to safety signals.

THE COURT: Necessary according to whom? According

to what authority?

MR. ROTMAN: According to Dr. Eisenberg based on his expertise in clinical epidemiology.

THE COURT: Well, but how does a clinical epidemiologist have expertise to opine on what the duty is of a corporate medical device manufacturer?

MR. ROTMAN: It's not about duty. As I said, the same point can be made without using the word "should have" or without using the word "duty." The same point can be made using a statement like, Patient safety is compromised when a manufacturer has information about a safety signal that is not followed up with studies. Or Patient safety is compromised when a manufacturer has information about -- about complications and risks in its product which are not passed along to physicians. And informed consent, which is necessary for the doctor-patient relationship and is the foundation of medicine, is compromised when a medical device manufacturer does not pass along information about risks.

So if the problem -- if the issue here is the "should have" opinions, plaintiffs are very comfortable with a stipulation that these statements by Dr. Eisenberg at trial will be recast in a way that he's not talking about duty and he's not talking about their obligation, but he's talking about the consequence in terms of patient safety and in terms of informed consent of not -- of not doing the necessary

studies to follow up on safety signals and not passing along information about risk.

THE COURT: Well, let's take that point you made for a moment.

So let's assume for a minute there's a doctor who gets on the stand and says "My opinion is patient safety is compromised if a large medical device manufacturer has safety signals and does not conduct a large prospective safety study and randomized controlled clinical trials," which are words right out of his report. Why is that relevant to the jury?

They're not going to be asked to decide whether or not Bard compromised patient safety. I don't think that's the issue in the case. The issue is going to be whether they defectively designed the product, which presumably includes testing that leads to design and, in the Booker case, whether they failed to warn a doctor.

What the doctor is opining about is, whether you say it as patient safety is compromised, he's still saying they should have done a study, should have done controlled clinical trials. And he's saying to the jury, "As a doctor, I'm telling you this manufacturer should have done that."

MR. ROTMAN: You're -- you're going back to "should have" when I'm saying we can leave that and talk about a different way.

THE COURT: But it's the same message, isn't it?

MR. ROTMAN: But the question is what's the relevance? Have we decided there's not negligence in this case?

THE COURT: Well, there's a negligent failure to warn and a negligent design defect claim in the case. I went back through them and I don't think there is just a generic negligence claim. I haven't seen one in the master complaint. We can talk about that if you think it's in there, but I went through, when I did the jury questionnaire and rewrote the statement of the case --

MR. ROTMAN: So based on negligence failure to warn, these issues about investigation of risks and reporting and disclosing is part of warnings.

THE COURT: Well, but a negligence claim requires a duty. What you're saying is he can establish the manufacturer's duty by stating his opinion of when patient safety is compromised.

MR. ROTMAN: If the issue is that he's not qualified to address the manufacturer's duty, then that's going to have to come from somewhere else.

THE COURT: But isn't that exactly what his whole report is about? At least all of these sections?

MR. ROTMAN: No.

THE COURT: My problem is when I read it -- let me just read you the points I excerpted into my order, and I want

you to comment on these because this is where I'm getting hung up --

MR. ROTMAN: Okay.

THE COURT: -- and I want to get it right.

He says -- now, most of this is in quotes. Some of it's my words: In light of various safety signals, Bard had a responsibility to perform large prospective safety studies and randomized controlled clinical trials.

That's from about nine different paragraphs in his report.

MR. ROTMAN: If I can comment on that --

THE COURT: Let me --

MR. ROTMAN: Should I comment on that?

THE COURT: Let me go through this and then let you respond.

He devotes an entire section of his report, section 4K, to the responsibility Bard had to do safety studies.

He says that rather than conducting such studies, quote, Bard downplayed the documented high rates of adverse events with the Recovery and G2 filters and had a corporate policy to not share any of these complication rate analyses with anyone outside the company.

He states Bard looked for ways to avoid being forthright and spent time, money, and company resources on media company and PR for spin control.

He claims that Bard performed no studies because it did not want to know the answer. Quote, if you don't want to know the answer, then don't look, close quote. And that Bard effectively allowed patients to be experimental subjects.

What he's saying to the jury is, "It's my professional opinion that Bard had a duty to perform all of these safety studies and that Bard didn't do it because they didn't want to find the answer, they didn't want to spend the money, and they wanted to use the patients as guinea pigs."

How is that not an opinion about what Bard had a responsibility to do as a corporate manufacturer, and how Bard as a corporate manufacturer failed to comply with that duty?

MR. ROTMAN: So as written in his report, he is stating exactly what you just read, and he is addressing responsibility. Not as an ethical responsibility but as what's necessary for patient safety, for informed consent, for pharmacovigilance, and to comport with its own internal standards. Its own internal standards as articulated by its president and other high officials.

If the problem is the Court doesn't want to the jury to hear this expert talk about obligation or duty in those terms, there's still an important relevant and appropriate statement based on his expertise that can be articulated based on the foundations that he established, and those -- much of what the Court read are not just opinions from -- that he's

grabbing out of the air, they're opinions based on support, and he cites the support for them.

And so the point is, if this will satisfy the Court's concern, tell us to go back and take out those obligation sentences and take out those "should" sentences and change them to -- to avoid any reference to obligation or duty.

THE COURT: What would they then say?

MR. ROTMAN: They would then say, "Failure to do a study compromises patient safety." "Failure to pass this information to doctors prevents necessary informed consent and prevents meaningful informed consent and is inconsistent with the company's own internal standards articulated by its president and other high officials."

So that is an example how it can be done.

THE COURT: The middle of the three ideas you just expressed where he would say failure to inform doctors prevents informed consent seems to me like a fair opinion for a doctor to give. He's saying "If I don't get the information, I can't confer with my client and get informed consent."

By the way, I think by my count we have seven experts giving opinions on that issue. We're going to have to talk about that.

MR. ROTMAN: Because this is an MDL, we're --

THE COURT: I know you have to have lots of

coverage --

MR. ROTMAN: Need a bullpen. Right.

THE COURT: But on the other two points you made, failure to perform a study compromises patient safety, how is that different from him saying Bard should have performed a study?

MR. ROTMAN: Because it's -- it's up to the jury to decide that. He's not saying it. He's saying that there's a consequence based on his expertise of not doing it and I'm explaining to the jury -- he's explaining to the jury what that consequence is.

And the source -- the -- there's different ways to view a set of issues and it's not limited to, well, you either say you have the duty to do it and you didn't do it or you say nothing. And what we're saying here is a clinical epidemiologist who's reviewed the file and has familiarized himself with the facts and with the literature and is very familiar with patient safety pharmacovigilance issues can opine and point out to the jury that there are consequences to this lack of followup.

THE COURT: Okay. I understand that point. I want to thank about that. I appreciate you explaining that. Let me ask a question related to that.

How does that expertise allow him to render opinions about why Bard did certain things? Such as they did it to

save money, they didn't want to know the answer, they wanted to use patients as guinea pigs. How does his medical expertise allow him to form those opinions?

MR. ROTMAN: He has a sophistication in -- in what -- of what's going on based on his review of a substantial amount of internal documents.

Now, issues like that are the kinds of issues where there might be statements like that where the Court's going to say we're not going to permit this or not going to permit that, and there's certain statements like the one -- like the one you just mentioned about if you don't look you won't find, or however that was phrased. If the Court doesn't want that, then we could certainly, on a specific point-by-point basis, not have him say these things at trial.

He was -- he was given the documents, he reviewed them, and this is what his take was. And it -- it's -- different judges might have different views of whether that's something that the jury should hear from this witness or not. He put it in. If it's going outside of a boundary for Your Honor, then it can be cut back. The point is, there's a lot of meat in the Eisenberg report that you wouldn't want to throw out the baby with the bathwater. That's my point.

THE COURT: Okay. Did you have other points you wanted to make? I kind of highjacked your argument.

MR. ROTMAN: That's fine. I'm pleased you did ask

the questions. I think that was helpful to the Court and that's why I'm here.

So, again, this whole thing about ethical, the -- Bard took a deposition where they asked a lot of questions --

THE COURT: Maybe I can save some time on this. I don't find this discussion about ethical or unethical helpful. To me the key is what I just talked about --

MR. ROTMAN: Okay.

THE COURT: -- what is the basis for a specific opinion.

I've read the deposition excerpts. I know the ethical question -- or the "ethical" word was often introduced in the question. But, to me, it's not a matter of ethics. The question is when he's opining that the corporation has a responsibility or duty, what is the source of that and is he an expert to give that opinion. That's the focus for me.

MR. ROTMAN: Okay. So the focus, Your Honor -- to the extent that the Court is interested in the fact that in this deposition Dr. Eisenberg was not what was pushing -- in this deposition, Bard was aggressively trying to get him to say, yes, this is an ethical -- this is an ethical obligation, those are not in his report and he was pushing back on that.

And I put together a compendium of excerpts and highlighted them so if the Court wants to see he was specifically saying, "Look, I'm not an expert in ethics and

what's the reason for my opinion is X," something other than ethics, that's available to the Court, too. So there's those two compendiums.

On the issue of the Trasylol case, that's, again, all about ethics. If the Court's not interested in that, I --

THE COURT: It's phrased that way. So is the Rezulin case it relies on. But I think it's the same issue, which is what's the source of the duty the expert is discussing and is there a foundation for it. Which, to me, is the more helpful way to think about it than just ethics versus not ethics.

MR. ROTMAN: All right.

So I would say -- what I was going to say about the Trasylol case is simply that the court didn't -- we don't know what the report said. And we know that the court says it looked at it and concluded that this was really his ethical opinions.

What I'm saying is in this case we have his report, and, as the compendium will show, Dr. Eisenberg makes it clear that he has these four foundations for these types of opinions. And if it comes back to the issue of what's his authority for saying X is necessary for patient safety or X is necessary for informed consent, those opinions at trial can be recast so that we're not talking about duty or obligation.

I would also like to briefly address for the Court the other issues that Bard has challenged in Dr. Eisenberg's

opinion, his reliance on internal documents. Again, we'll rest on our brief and the Court's prior decisions on that. Common sense opinions. We recognize that Eisenberg's testimony should be limited to that which is needed to assist the jury and matters that are common sense to jurors and which do not require an expert are not proper subject matter, and so we don't believe he's addressing issues that are common sense. But to the extent that there are individual points that might concern the Court in that regard, they can be addressed in an isolated fashion or taken up at trial based on those broad principles.

Other physician's expectations, similarly, that was addressed by a prior -- by prior orders. We agree with that. And Dr. Eisenberg's opinions about informed consent and what doctor's need and expect for informed consent.

And then it's parallel -- or the corollary of that is then, therefore, what's necessary for them to receive from the company. The Court has already said those types of issues are appropriate and what is more problematic is when an expert testifies about what other doctors would do if they had the additional information.

So, again, we believe Dr. Eisenberg will toe the line at trial and stipulate that he will toe the line at trial in terms of physician expectations to follow the guidelines and parameters set by the Court.

THE COURT: All right. I'm happy to look at the compendiums if you want to give defense counsel a copy --

MR. ROTMAN: Yes. So the first compendium I'll hand the Court and opposing counsel is the excerpts from the Eisenberg report.

And the second will be excerpts from the deposition that show that Dr. Eisenberg was not merely going along with the suggestions that everything was an ethics opinion, but rather was -- was based on the foundations that I mentioned and that are mentioned in his report.

And the third thing I have are portions of his deposition -- and, again, these were not part of what the -- what Bard pointed out when it was doing the recitation of his deposition.

By the way, there's one other thing, Your Honor, that you brought up that I didn't address, and that is he cites to guidelines that say "ethics" in them, and so -- as authority. And I think it's misunderstood what they're there for. They're there for establishing objective standards for what doctors need to give informed consent. That's not in a vacuum. They need the information. The reason it's there is because there's the objective standard of what the doctors need. It's not there because it's a standard for what the medical device manufacturer's obligations are. It's there because it's an objective standard of what the doctors need,

and that is part of the equation for saying, okay, if this is what the doctors need and this is what they expect, then the jury has information about what kind of disclosures were required.

So it's sort of a two-step process to say, well, he cited these because these are authority for Bard's duty, it kind of misses the nuance of what was intended.

And so -- and then the third compendium I have, Your Honor, is further excerpts from the deposition of Dr. Eisenberg where it was really -- a lot of it is from the redirect where he testified about his expertise in clinical epidemiology and his focus on patient safety, informed consent, the nonbinding nature of these guidelines but why he used them, and common sense issues that are raised in the -- by the defendants in their motion, and also pharmacovigilance issues.

In each of these, Your Honor, I highlighted so that the Court and counsel are looking at the same thing and the highlights make it so that the -- so that the Court can see why these are attachments. And I did the highlights in all three hand-ups.

MR. BUSMAN: Mr. Rotman, there's no highlighting in this.

MR. ROTMAN: I may have given the Court two copies.

THE COURT: You did. You gave me three.

MR. ROTMAN: Thank you, Your Honor. I have no further presentation unless the Court has questions.

THE COURT: Okay. Thank you.

MR. ROTMAN: Your Honor, would the Court like the plaintiffs to submit a revision of the Eisenberg report on certain issues?

THE COURT: No.

MR. ROTMAN: Okay. Thank you, Your Honor.

MR. BUSMAN: I think Your Honor's discussion about duty was instructive, and I'd simply note that none of the proposed stipulations change the basis of these opinions which are contained in the section of the report that Your Honor did have an opportunity to read.

Plaintiffs still have yet to articulate any duty that would be binding on Bard. And, in fact, Dr. Eisenberg has admitted that the objective standards that he cites in his report are not, in fact, binding on Bard.

That said, unless Your Honor's got additional questions, I've got nothing further.

THE COURT: All right. Thank you.

Counsel, let's run through a few additional issues.

As I mentioned a moment ago, and I think this is understood by all, my intent at trial is to have one expert per subject. I don't think there's any reason we should take the jury's time with more than one expert stating an opinion.

And so that will be the approach I will plan to take.

We have now remaining, after I rule on these four motions, I think six additional motions that are focused on expert testimony: There's the motion directed at Garcia and Streiff or Streiff, S-T-R-E-I-F, that's one motion; there's the McMeeking M-c-M-E-E-K-I-N-G motion; there's the Ritchie motion; there's the Morris motion; the Grassi, G-R-A-S-S-I, motion; and then the motion on the use of criminal law standards.

And my understanding from what you communicated to my office after the last hearing is that you're okay with my ruling on all of those without oral argument. Is that correct?

MR. NORTH: Yes, Your Honor.

MR. LOPEZ: Yes, Your Honor.

THE COURT: We'll get the decisions from today's hearing out next week and then we'll just start getting those out to you. My hope is we can get all those done before the end of February so you'll know in advance, well in advance, hopefully, of the final pretrial conference where I've ruled on those.

We've got several summary judgment motions that are still pending with respect to bellwether plaintiffs that we will address when we approach those bellwether trials.

The motion in limine filed by the plaintiffs on the

FDA 510(k) clearance that's been referred to as the *Cisson* motion is being briefed. It's going to be briefed by the end of January. I saw, I think, in your joint report a request there be oral argument on that; is that correct?

MS. REED ZAIC: Your Honor, the plaintiffs' position is, because of the timing that we're bumping up against, which I'm assuming, I hope not gratuitously, why the Court is bringing this up, we're bumping up to the time of trial, plaintiffs would be willing to forgo oral argument unless the Court would like us here at any time, we could do it telephonically, to answer any particular questions.

THE COURT: Okay. How about the defense?

MR. NORTH: Your Honor, we defer to the Court's preference on that.

THE COURT: All right. Let's assume, then, that I'm going to decide that without oral argument. If I think I need it, we'll schedule a phone conference so I can get each side's views.

MS. REED ZAIC: Yes.

For the court reporter, Julia Reed Zaic.

THE COURT: Thank you.

Okay. That takes care of all of the pending motions. There's one motion to substitute a party in an individual case that we don't need to deal with.

The defendants indicated you wanted to file an

over-length motion in limine. What's going to be the topic on that one?

MR. NORTH: Your Honor, we were not asking to do it early so much as just page expansion. We can do it with a regular time frame.

The import of that one is the scope of evidence regarding the Recovery filter that should be admissible in a case like Ms. Booker's which involves the G2 filter.

THE COURT: Okay. How many pages do you think you need on that?

MR. NORTH: We would just ask for the same that they got on their FDA motion. And we would try to take less than that.

THE COURT: What was that?

MR. NORTH: I think it was ten.

Was it?

MS. REED ZAIC: I believe you gave each side ten and five pages for the plaintiffs for reply.

MR. NORTH: It's in the Court's last order. I can find that.

THE COURT: That's all right. Let's say it will be 10, 10, and five.

And we'll just -- well, let me think for a minute.

Under our existing schedule, motions in limine are due on January 26, and responses are due on February 9th. And

I didn't set a reply brief date because I typically don't have reply briefs on motions in limine.

Do you think you need one on this one, Mr. North?

MR. NORTH: No, Your Honor. I think we can do without.

THE COURT: Okay. So let's just say 10 page motion, 10 page response.

And, as you know, these will all -- well, to the extent they're clear and I think I can rule, I'll try to rule before the final pretrial conference. Otherwise, I'll want to hear any argument on them at the final pretrial conference.

Plaintiffs would like to file a motion in limine on a nonparty at fault in the Booker case; is that right?

MS. REED ZAIC: Correct, Your Honor.

THE COURT: And can that happen under the regular schedule? I think you wanted five pages?

MS. REED ZAIC: Yes. We want just two additional pages, Your Honor. My understanding, there's no objection from the defense.

THE COURT: We'll say five page motion and five page response on that issue.

MS. REED ZAIC: Thank you, Your Honor.

THE COURT: And I'm assuming this is the Georgia nonparty at fault statute?

MS. REED ZAIC: Yes, Your Honor.

THE COURT: The bifurcation motion. As I understand what you said in the papers, Mr. North, your understanding of that bifurcation under Georgia law would be that the only thing we reserve for a second hearing is evidence on the defendants' worth; is that right?

MR. NORTH: Yes, Your Honor. Generally speaking, that's how it operates.

THE COURT: So whatever evidence they're going to rely upon to argue whatever the Georgia standard is for punitive damages would come in during the first part of the trial.

MR. NORTH: Yes.

THE COURT: All right.

And what you would propose is that we would ask the jury after the first part of the trial, do you believe that the standard for punitive damages has been met? If they say no, we don't have the second part. If they say yes, then we put on evidence of Bard's worth and the jury decides the amount.

MR. NORTH: Yes, Your Honor.

THE COURT: Okay.

Yeah. I think we ought to brief that. I know nothing about Georgia law. I'm happy to consider it and whether it applies here.

We're still going to have to do it within that time

period we've set for the trial. We're still kind of boxed in by the fact by that first week in April I've got to be out of Phoenix at --

MR. NORTH: I would say, Your Honor, I've never personally, even though I am a Georgia lawyer, fortunately, thus far, I've never been involved in a Georgia case that went into that punitive damage stage. But I'm familiar with some. And the punitive damage phase under the Georgia procedure often takes an extra hour or two hours. It's not a lengthy process because the evidence is so limited and there might be ten or 15 minutes of argument or something like that. But it usually does not add to the length of the trial anything significant.

THE COURT: All right.

I think we should brief it.

Let's do it on the same schedule as the motions in limine. Let's have defendants file the motion for bifurcation, have the plaintiffs oppose. So it would be January 26 and February 9th for the response.

MR. LOPEZ: Your Honor, I'm not sure we're on opposite ends about this issue. I think, at least as I read our -- what we've proposed, the evidence comes in, and whether or not that's punitive or not will be in the eyes of the jury. And the second phase is purely focused on the amount of the net worth and the basis for and argument as to what the

plaintiffs believe should be an appropriate amount of punitive damages. I'm not even sure what we're briefing so --

THE COURT: So you're in agreement it should be bifurcated?

MR. LOPEZ: The second -- I read Georgia law. I agreed in the statement that it's pretty clear. We got advice from Georgia counsel -- pardon me?

They're telling me to wait to see the brief.

Your Honor, look, again, I wouldn't be standing up saying this just in a whim. I've spoken to Georgia counsel. It's pretty clear when you see Georgia law that the second phase of this is going to be the amount of punitive damages. The bigger issue is what evidence are we going to have for that second phase of trial.

THE COURT: Well, we'll talk about that in just a minute.

MR. LOPEZ: Sometimes the motion is anything that tends to be something that goes to punitive damages we can't put that evidence in. And then you've got to -- you've got to draw the line. Usually people don't know where to draw the line.

THE COURT: I understand defendants are not say evidence of defendants' conduct would be reserved for the second part, only evidence of defendants' net worth.

MR. LOPEZ: Right. Again, that's --

THE COURT: Let's do this --

MR. LOPEZ: I would prefer to hear how much money they're worth in the first phase of the trial, Your Honor, but Georgia law seems to be pretty clear that that's in a different phase.

Now, we want the same jury, of course, to consider that part of the evidence.

THE COURT: Well, it's going to happen in the same trial, it's going to happen with the same jury, and it's going to happen under the time limits. So your 27 hours and your 25 hours would have to include whatever time you want to spend in that second phase.

MR. LOPEZ: Right.

THE COURT: Let's do this: Let's say you confer. If you can agree that's the right approach to take, then don't file the brief on January 26. If there's a disagreement then go ahead and brief it.

But it will be with the understanding that we're still doing it within these time limits, which means you'll have to rest at 26 and 24 hours so you've each got an additional hour for the net worth issue. And I'm okay with doing that if you all agree that's the right approach.

All right.

MR. LOPEZ: We'll confer and maybe draft a stipulation, Your Honor.

THE COURT: Okay.

The second issue -- or I should say the other issue on the punitive damages is, as I understand, a request from plaintiffs to conduct discovery on the net worth issue.

I will tell you, Mr. Lopez, when I read that, the question that popped into my mind is that's fact discovery. We had a fact discovery period. Why wasn't that done during the fact discovery period if you knew you were going to be seeking punitive damages?

MR. LOPEZ: Well, because I think if we would have asked for that kind of discovery before you ruled on the motion for summary judgment as to whether or not we were going to get punitive damages, they would have said it's too soon for us to take that kind of testimony.

We just did this in the Florida case that we had set for trial last week. Right after the motion for summary judgment -- not last week. Last year. The motion for summary judgment, once it was denied we approached the court and the court agreed to give us a deposition. We put it together very quick. I think it was an hour, hour and a half.

Not to mention there's been a significant change of circumstances with this defendant. I mean, they've now been purchased by another corporation. And whatever amount of information we may have gotten regarding this company's financial status is significantly changed since we took that

deposition on January 26, 2017. So the Court will recall that we just received our ruling allowing us to have punitive damages I think the end of November. We're talking about a two-hour deposition.

THE COURT: Well --

MR. LOPEZ: The announcement of the final acquisition by Becton Dickinson was December 29, 2017.

THE COURT: What I'm not understanding, because I haven't gone back and looked at it, is did I rule that you can do punitive damages discovery at some point?

MR. LOPEZ: Not that we could do discovery, but you -- they made a motion for summary judgment to get punitive damages out of the case. We won that motion. And I can just tell you --

THE COURT: That was back at the end of 2016?

MR. LOPEZ: No. '17. We just got that ruling, I think it was the day before Thanksgiving.

THE COURT: Are you talking their preemption motion?

MR. LOPEZ: No. The Booker motion --

THE COURT: Oh, in Booker specifically.

MR. LOPEZ: Yes.

THE COURT: I'm sorry, I thought you meant in the case as a whole.

MR. LOPEZ: No, no. The Booker motion for summary judgment. It was just granted --

THE COURT: What is the January 26, 2017, deposition you're referring to?

MR. LOPEZ: We had a trial in Florida, state court Florida, scheduled for end of February, March. The same motion for summary judgment. Ruled in our favor. After it was ruled in our favor we asked the Court to allow us to take a deposition like the one we're suggesting here. The Court allowed it. I think we asked for two hours, the Court gave us one.

I mean, the financials -- obviously, if the financial status of this company was basically the same today as it was then, we probably could live with that deposition, but there's been significant changes in that status, I mean significant, since then.

THE COURT: Okay. I understand what you're saying.

MR. LOPEZ: Usually, Judge, they won't allow you to ask questions like that before it becomes relevant. It only becomes relevant if the court allows punitive damages. That's been -- that's pretty consistent.

THE COURT: Okay. I understand your position.

MR. NORTH: Couple points, Your Honor. First of all, with all due respect to Mr. Lopez, in Florida there is a specific procedure, as I understand it, that says discovery about net worth cannot be conducted until the court makes a threshold determination that punitives are available.

That's obviously not what we have here. We had a lengthy fact discovery period, we had a lengthy case specific fact discovery period for the five bellwethers, and not once did they do that.

I really am reluctant to be chasing around on depositions. Here we are almost six weeks before trial when we are engaged in trial preparations. I think it's disruptive.

But I think I have a proposal that ought to satisfy them and render this question moot. I've consulted with my client. The last available data as to C.R. Bard's net worth are the third quarter 2017 quarterly reports, SEC filings, as to assets and net worth and all of the value of assets/liabilities. It's all there in the SEC filings. Why can't we just provide them -- they're public records anyway, but I can obtain a copy of those, give them those filings, and then they've got the best available evidence that there is at this point.

THE COURT: And would you stipulate to their admission?

They need a witness if they're going to present the evidence or need stipulation of what comes in.

MR. NORTH: I'm reluctant to say, Your Honor, only because I haven't seen the document. I need to look at the document. I suspect I would because that evidence -- if we

got to the punitive phase, that evidence would be relevant. So it's just a matter of stipulating as to the form of it.

THE COURT: What about their point there's a new parent corporation?

MR. NORTH: I did want to bring that up with Your Honor. There is a new parent corporation, Becton Dickinson. First of all, Becton Dickinson is not sued and should not be sued in any of these cases.

My understanding, and I did some due diligence to be able to represent this to the Court accurately, I believe, that C.R. Bard incorporated is still a separate corporate entity. Bard Peripheral Vascular Incorporated, the other defendant here, is still a separate corporate entity.

Bard Peripheral Vascular remains a wholly owned subsidiary of C.R. Bard. In turn, C.R. Bard now is a wholly owned subsidiary of Becton Dickinson.

So the only change we have is Bard now has a parent company. But it is still a separate corporation and BPV is its own subsidiary. So there's no change for purposes of what would be relevant for this jury, and the value of Bard is what would be relevant. Certainly not the value -- we would object strenuously to any suggestion, if they were to make it, that the net worth of Becton Dickinson should somehow be relevant here.

THE COURT: Mr. Lopez.

MR. LOPEZ: I think the last thing he said is probably what we should focus on, and that is the value of -- we're fine with the value of C.R. Bard. The third quarter financial report from this company is not going to tell the true story of the value and the financial status of this company when this -- should this case go to the jury on punitive damages.

This deal closed the end of December. C.R. Bard received like a 4 -- I don't misquote this, Mr. North, I'm just reading what's in the newspaper. Got a premium on their stock of about somewhere between 4 and 6 billion dollars. That's not going to be reflected on their third quarter 2017 financial statement.

What I'm suggesting, Your Honor, I don't mind working this out with a stipulation and with documents that we can have, if we need an expert to look at them and say these accurately reflect the net worth and financial status of the company and we've agree that that document can come in the way -- or we have an expert testify to it, I don't care. But I'm not going to accept a third quarter financial statement of C.R. Bard for their current financial status what or what it might be, you know, a month from now.

I know we've got to stop somewhere, but it's not going to be the third quarter of 2017 when we're looking at a 4 to 6 billion-dollar premium.

MR. NORTH: I would just note for the record, Your Honor, if there was a 4 to 6 billion dollar premium, and I don't know what the number was, that wasn't paid to C.R. Bard, that was paid to the stockholders, because C.R. Bard was purchased by Becton Dickinson. It doesn't affect the value of the company, it just affects what the former Bard stockholders received.

But the fact of the matter is that the third quarter, as I understand it, financials are the best we have right now. There are no financials for C.R. Bard entity that have been computed for the fourth quarter as of yet. There may be prior to trial and I can find out the time frame for that, if they're still doing that now that they're a wholly owned subsidiary. I'm not even sure about that. I can find that out.

But I was told in no uncertain terms, and I trust this to be correct from in-house counsel, that the latest data they have is the third quarter data.

These payments that Mr. Lopez are talking about wouldn't have gone to Bard stockholders. They don't have anything to do with the value of the company as it exists today or as it existed then.

THE COURT: All right. I understand your positions. I want to think about this. I'll put something in my order after today.

All right. So let's talk just a minute about the overall schedule to make sure we're all on the same page.

We're going to get -- you know the schedule for the jury questionnaire stuff. We went over that last week. That order went out. The jury questionnaires have been mailed. That's all in the works.

Motions in limine are due on January 26. Responses February 9th. We have moved the date for the final pretrial order to February 23rd, and the final pretrial conference is now set for March 2nd.

Traci, would you look at March 2nd. We set it for 2 p.m.

THE COURTROOM DEPUTY: Yes, 2 p.m.

THE COURT: I think we need to have it start earlier than that. Is there time in the day --

THE COURTROOM DEPUTY: All day.

THE COURT: Let's set it at 10:00 a.m. on March 2nd, if that's all right for everybody, just because I want to make sure we've got time enough to cover all of the details that we need to before trial.

And I think that's everything we've got scheduled. We don't have any other hearings set. So the next time you would be in this courtroom would be the final pretrial conference on March 2nd.

Are there any concerns about that? Do we need to

have a status conference in mid-February just to make sure we're not missing issues?

MR. LOPEZ: Well, one second just in response to that. I hesitate to say this because it's going to sound like I'm asking the Court to rush something, but I think I should bring it to your attention. A lot of what we're doing, the documents, the deposition cuts, even the witnesses, are going to really depend what kind of ruling we get in the pending motions before you on the FDA presence in this case, via *Cisson* and all those other cases that we cited.

I don't know whether to ask you when you think that might be.

THE COURT: Why don't we do this -- that's not going to be fully briefed until the 26th, I think.

MR. LOPEZ: We'll try to get it in sooner, right?

MS. REED ZAIC: I'm doing my best to get it to you by Tuesday, Your Honor.

THE COURT: Okay. How about if I just say we will rule on that before the other expert motions. Because I understand that one really does affect the overall nature of the trial. So we'll move that to the front of the queue and as soon as it's fully briefed we'll get it done. We usually can get a matter decided and out within a week. I'm guessing you'll have it certainly before the middle of February.

MR. LOPEZ: Let me ask you this, then, Judge. I

don't want to move dates but we may have to because we're supposed to get together by the 9th. Mr. North and I just spoke about this trying to figure out the date, time, location to put together our joint exhibit list and make sure we don't have duplicates and get those marked. That is going to change dramatically depending on a ruling like that.

So we can do it as if we -- neither side knows and then we can go back and start pulling things out. I'm just thinking of a more efficient way of us to do it as parties --

THE COURT: What I don't -- what I don't want to push off is the February 23rd submission date for that stuff because I need it a week before the final pretrial conference. So if you all think you can get it done starting later than February 9th -- you're optimistic.

MR. LOPEZ: We're not -- I don't think -- we're well on our way. I mean, we are ready. But I think before the defense and we can put that together in what would ultimately be the Court's exhibits, I think we need to have that. So if we can have relief on the February 9th. We don't want to move the February 23rd any more than you do. But it could be we may have to. We may have to move that goalpost a little bit, Your Honor.

THE COURT: Well, I think what you are talking about is one of my orders which says you have to meet two weeks -- yeah. It's paragraph C(6) in Case Management Order 28. You

have to meet in person no later than 14 days before submission of the final pretrial order.

MR. LOPEZ: Right.

THE COURT: You're experienced attorneys. If you don't want to do it on the 9th, that's okay. But what I'm confident I won't see here but I see too often is we get to the final pretrial order that gets submitted and then I hear at the final pretrial conference, oh, you know, we left out some stuff, or we had this dispute and never worked it out, and you defeat the whole purpose of the final pretrial order when you do that.

So if you all want to do it a week beforehand and just make sure you put in whatever time is needed to get it in to me by the 23rd, that's okay.

MR. LOPEZ: Okay. Your Honor, thank you.

MS. REED ZAIC: Thank you, Your Honor.

THE COURT: Let me mention something else while its on my mind and then I'll hear from you, Mr. North.

There was a suggestion made during one of the arguments today that there may come a point in trial where we would hear testimony from an expert with the jury out of the courtroom to establish foundation. I will just tell you if that becomes necessary -- I've never done that. But if we were to do it, the clock's still running on your time.

MR. LOPEZ: On the challenger?

THE COURT: Pardon?

MR. LOPEZ: We actually had a conversation about that. Would it be the person challenging or --

THE COURT: I don't assign it 50/50. I assign it to, in my judgment at the time, the party responsible. So, like, if we have a ten-minute bench conference, if you all go back and I think that was totally frivolous objection, I give all ten minutes to the person who made the objection. If I think that was a well-founded objection, we didn't need a bench conference, I give it to other side. I just make my best judgment along the way. And I would do the same thing if we had to send the jury out to hear from an expert.

I only mention it because we can't afford to spend time with the jury outside of the room and still get the trial done in the amount of time we do unless the clock is running while the jury's out of the room.

I won't run the clock when we're meeting in the morning or meeting after the jury has gone home for the day. But if it's during those trial hours, we're going to be counting everybody's time.

MR. LOPEZ: All right. Understand.

THE COURT: Mr. North, you wanted to raise something?

MR. NORTH: Your Honor, I was wondering if I could beseech the Court to allow me to ask for reconsideration on the question of that reply brief to that one motion in limine,

and maybe if we can just file a five-page reply brief, if we thought necessary, within seven days or their filing. The response would be due February 9th. We would file a reply by February 16th, if deemed necessary.

THE COURT: And that's on your motion in limine --

MR. NORTH: Right. Scope of Recovery filter --

THE COURT: Recovery. That's fine.

MR. NORTH: Okay. Thank you.

THE COURT: Did we set a date for when you're going to file that notion? It's just January 26; right?

MR. NORTH: Right.

All right. So that reply, if you need it, will be February 16th.

What else do we need to address? Anything?

MR. O'CONNOR: Your Honor, I was just reminded Jones is coming up pretty quick, too, and there is, as you noted, an outstanding summary judgment on that. We think that -- we request you start to consider a date that we can have an oral argument on that with that trial coming up May 15th just on the heels of that.

THE COURT: I don't think I'm going to be able to give you one. I'll do my best, but the reason is we finish trial on March 30th and I get on a plane and I'm gone for three of the four weeks in April. I've got to be at every advisory committee federal court meeting around the country

that three weeks. So I'm back the last week, maybe it's the third week, of April and it's just jammed, as you can imagine. And then we're into May, which is when Jones is to be heard. And you certainly don't want to be getting my motion for summary judgment ruling in early May, I don't think.

MR. O'CONNOR: No.

THE COURT: So I honestly don't know how to do it. I suppose we could try to set it before the Booker trial, but that's -- we've got a pretty full plate with everything else we're doing and that, to me, is a lower priority.

MR. STOLLER: Your Honor, I'm sorry, we're conferring over here.

THE COURT: I can tell. Go ahead.

MR. STOLLER: The obvious concern we have is that trial is going to go forward May 15. We're today four months from the trial. Obviously everybody on both sides of the aisle would like some clarity in terms of what counts are going to go forward in that case, and if we wait until after Booker we're at the six-week mark. And I don't have my calendar in front of me, but my guess is we've probably got pretrial order due to you in that case sometime in the middle of April.

THE COURT: We haven't set it yet.

MR. STOLLER: Right. But regardless, May 15, I'm just working back from that date. Realistically, for us to

get there we've got to find a way to get that resolved more than -- well, probably before the Booker trial starts, would be my guess. Realistically to do the things that need to be accomplished to get Jones ready for trial.

THE COURT: Well, I understand what you're saying. All I can say is I -- I think you want rulings on all of the *Daubert* motions. I'm going to have to rule on all of the motions in limine. I've got 350 other cases. If I can get it done, I sure will.

But to me -- maybe you disagree with this. To me, the Jones summary judgment ruling is a lower priority than the remaining *Daubert* motions and the remaining motions in limine.

MR. LOPEZ: Yes.

THE COURT: Does anybody disagree with that?

MR. O'CONNOR: No.

MR. STOLLER: No.

THE COURT: So if I can get through all of that in February and have time -- or early March and have time to decide Jones before the Booker trial starts, I will do it. I just honestly don't know if I'll have time.

MR. O'CONNOR: Well, I guess the only point there is Jones, like Booker, is Georgia law, so --

THE COURT: What I thought you had originally said, you want a hearing on it. I don't think I'm going to be able to squeeze in a hearing. But I can do my best to get it

decided before we start the Booker trial.

MR. O'CONNOR: That's fine.

MR. LOPEZ: I think it's the same motion as Booker.

MR. O'CONNOR: I think there's was -- it's pretty close. Yeah, it's pretty close to the Booker motion, as I understand.

THE COURT: Okay. Well, maybe it won't be as much work, then, as a typical summary judgment motion.

The last thing that occurs to me, and then I'll be happy to hear your point, Mr. Lopez, is we need to be thinking about the third bellwether trial. I have had two judges on this court volunteer to take a bellwether trial this year.

My anticipation has been that we would do the third bellwether trial sometime in the summer. Probably in August. And I don't know if I could do it or if I need to get another judge to do it. My thought is we'd then do a fourth bellwether trial in the fall. Probably with another judge because my fall is pretty jammed up.

And we would then have four of the bellwether trials done this year and we'd get the other two done early in 2019. Obviously, we need to still pick the sixth.

Do you have thoughts on that overall schedule and on the idea that we talked about briefly once before of having another judge step in to do a couple of those?

MR. LOPEZ: I know we've had this discussion before,

Your Honor. Plaintiffs are fine with that.

MR. NORTH: We're fine with that, Your Honor.

THE COURT: Okay.

My intention would be to have that judge -- or put in a form where that judge can review all of my rulings on the *Daubert* motions, all of my rulings on the motions in limine, and I would keep track of significant evidentiary rulings I make in the other two bellwether trials so I can share them with that judge. Obviously that judge would make his or her own decision on issues at trial, but at least they'd be educated by what we've done in the first couple of trials.

Mr. Lopez, did you have another point?

MR. LOPEZ: Yes, Your Honor.

I know this issue keeps coming up about whether or not we have a negligence claim, and it's clear we have two, at least two, causes of action with the title, I think it's negligent failure to warn and negligent design. Within the body of those two counts are a lot of general negligence type concepts. Concepts like failure to test, the marketing, the way they marketed the product. A lot of things that, if you had a general negligence count, you'd probably put it in there. They're fashioned under design and failure to warn.

So my comment to you, Your Honor, is that those two causes of action, even though they may be -- they may sound in failure to warn or design, allege general negligence concepts.

Now, those two counts were not challenged in summary judgment, there's not been a demure brought against those to change the language or motion to strike or motion -- in other words, there's been no motion on the allegations as they're set forth in those two causes of action.

So I think it is plaintiffs', certainly, position that to the extent Georgia law would allow both a general negligence count or instruction to a jury in addition to negligence for failure to warn and design. I just want to make sure Your Honor knows that we want to still be able to get in evidence that deal with those allegations as they're set forth in those two causes of action, even though they may sound in general negligence.

Let me put it this way: They all relate to those causes of action. In other words, the fact you have a negligent design, if you're negligent in the way you test, you're negligent in the way you go about your investigation and due diligence, I understand that goes to the design, but you and I have had this discussion before about whether or not we have a general negligence cause of action. Technically we do even though we don't title it that in the master complaint.

THE COURT: Well, let me ask you a question on that, Mr. Lopez.

Give me, if you would, a 60-second argument you would make to the jury on how they should find Bard negligent that

does not relate to a design defect or failure to warn.

MR. LOPEZ: Well, their marketing practices. I mean I think a large focus of our case is going to be on what they did with respect to the way they marketed this device. In other words, certainly the way they tested it. There's going to be significant issues about the way they tested. I understand that goes to design.

THE COURT: What is -- what is a negligent marketing claim that is different from a negligent failure to warn claim?

MR. LOPEZ: Well, I mean, you know, failing to warn is an issue of where they had an obligation -- they had an obligation based on what they knew about the product to warn doctors. And maybe what I'm really talking about here, Your Honor, and maybe the discussion we should be having, because I thought of it when you and Mr. Rotman were talking about Dr. Eisenberg and the fact that we have a pharmacoepidemiologist talking about patient safety, and the issue there is we still have a punitive damages count. And in Georgia, the law in Georgia, and there's a lot of things I can read, all the typical language of malice, but it's evidence that would raise the presumption of conscious indifference to consequence.

So there's going to be a lot of conduct. What I'm reacting to, Your Honor, I don't know if it was the last

hearing or the hearing before, you ask what does their conduct have to do with failure to warn or design defect. I just want the Court to understand that in our negligence causes of action, we're going to have a lot of conduct. I mean, in fact, plaintiffs' case is primarily going to be about conduct.

We're going to focus on the product and it's design, we're going to focus on the warnings, but one of the main focuses of our case is going to be what Bard did or didn't do in view of some -- the information they had about the risks of their products.

THE COURT: I understand what you just said about conduct. And I don't remember what I said at a previous hearing, but I understand that you are going to seek to put in evidence that Bard knew of problems in its product, that it didn't test them and therefore it didn't redesign them, didn't disclose these problems to doctors. That's all over the reports we've been dealing with. I'll obviously rule on what is or is not admissible along those lines as we get into trial.

What I'm struggling with is where we started, and that is this notion that there's some sort of negligence cause of action that the jury could find Bard liable on that does not involve a failure to warn or a design defect. I'm not seeing what that is.

I mean, if there's a negligent marketing claim, for

example, it seems to me that's the same as a failure to warn because the duty that you would define for the jury in marketing is a duty to be honest and truthful in marketing your product.

MR. LOPEZ: Right.

THE COURT: Same thing on failure to design. If -- well, let me state it this way: Let's assume for a minute that you convince the jury that Bard was really negligent in failing to conduct two kinds of tests and in conducting a third, but you don't convince the jury there was any defect in design. Are you suggesting that the jury could find Bard liable for negligent testing?

MR. LOPEZ: Well, let's put it -- what if, in fact, there's evidence that Bard spent more money on marketing than they did research and development. That Bard's first go-to response to a significant safety issue with their product was not to go to scientists to figure out what they had wrong or pull the product back to evaluate it, but to go to a PR outfit to determine how you're going to get that message out to the public and to the doctors. Or -- and what that message was going to say. And within the message was going to be how we can manipulate the evidence that we have about our product so that our company and this product does not have -- that news does not have an effect on our stock price or on the market share of this product.

I don't know that -- that's certainly not a design defect, and certainly not a failure to warn. That's a different type of conduct. I mean, that's conduct that certainly goes to punitive damages.

And -- but what if the jury doesn't think that's punitive? What if they think that conduct is you just shouldn't have done that, shame on you, you're bad, that's negligent, a reasonably prudent company would not do that. I mean, we should win that case, I think, if under those circumstances the jury finds that that's negligent and, well, doesn't have anything to do with the design or the warnings, and but -- but it maybe doesn't raise to the level that it's punitive damages.

THE COURT: Well, let's assume we gave them a series of interrogatories: Do you find that Bard product at issue was defectively designed? No.

Do you find that Bard failed to warn appropriate medical community? No.

Do you find that Bard is liable for punitive damages? No.

You're saying that the jury could nonetheless say we are going to hold Bard liable for $5 million because we don't like the way they did their business?

MR. LOPEZ: No. No. I mean, that's --

THE COURT: Okay, then finish my sentence. We find

they're liable for $5 million because --

MR. LOPEZ: They didn't properly test this. When they did test it, they used an inappropriate standard or threshold of safety. Of course, that's all design, isn't it?

THE COURT: Well, yeah. I mean, it seems to me testing only bears fruit in your claim if the product was improperly designed.

MR. LOPEZ: Right.

THE COURT: Otherwise -- and let's say they did a test completely negligently but the product was properly designed. That negligent test didn't harm the plaintiff.

MR. LOPEZ: Okay. Again, Your Honor, I know we've talked about this more than once. I'm still kind of reacting to the hearing we had two or three -- it was probably two hearings ago when you said what does conduct have to do with this case if we're only talking about warnings and only talking about design. And maybe I should just take comfort in the fact we still have a punitive damage claim in the case.

THE COURT: Like I'm saying, I don't remember what I was thinking, if I was thinking anything clearly, when I said that. But it seems to me you've pled a negligent design defect and negligent failure to warn claim and that everything -- in terms of causes of action, everything that's going to come in at trial has to focus on those claims. And you've also pled a non-negligent design defect and a

non-negligent failure to warn that are both still in the case as well.

MR. LOPEZ: And we pled, of course, punitive damages, which is conduct.

THE COURT: Right. But is not a separate cause of action.

MR. LOPEZ: Right. All right. Thank you, Your Honor.

THE COURT: Okay.

Other thoughts? Anything else we need to address?

MR. NORTH: Nothing further, Your Honor.

THE COURT: Okay. Let me just say this: Between now and March 2nd, which may be the next time you're here, if you think we need to talk through any issues that are coming up, give me a call and we'll set a telephone conference so that we can get those issues addressed before we get to the final pretrial conference.

All right. Thank you all.

MS. REED ZAIC: Thank you, Your Honor.

(End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 1st day of February, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter